IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC.,

a Georgia corporation, 6015 Unity Drive, Norcross, Georgia 30071,

and

JARED WHEAT, 6015 Unity Drive, Norcross, Georgia 30071,

Plaintiffs,

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993,

and

UNITED STATES
FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue, Silver Spring, Maryland 20993,

and

ALEX M. AZAR, II, as Secretary of the Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201,

and

UNITED STATES DEPARTMENT

COMPLAINT

Civil Action No. _____

OF HEALTH AND HUMAN SERVICES,)
200 Independence Avenue, S.W.)
Washington, D.C. 20201)
)
)
Defendants.)
)
_____)

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

COMES NOW, the plaintiffs Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), and Jared Wheat (collectively "Plaintiffs") by and through the undersigned counsel of record, and for their Complaint against defendants Norman E. Sharpless, M.D. ("Sharpless"), the United States Food and Drug Administration ("FDA"), Alex M. Azar, II ("Azar"), and the United States Department of Health and Human Services ("HHS") state as follows:

PRELIMINARY STATEMENT

1. This Action is one for declaratory and injunctive relief against the FDA and related defendants for their arbitrary and capricious action, without observance of procedure required by law, regarding the dietary supplement ingredient 2-Aminoisopheptane HCI, also known as, 1,5 DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine, but most commonly referred to as "DMHA". DMHA is found in the walnut tree

(*Juglans regia)*, one of the oldest tree foods known to man, and can also be synthetically produced much like a vitamin or amino acid.

2. As set forth herein, the FDA has long chaffed at the statutory/regulatory structure for dietary supplements, which does not require pre-market approval and puts the onus on the FDA to establish that a particular dietary supplement or ingredient is unsafe. Under the guise of "modernizing" this regulatory structure, the FDA has embarked on a campaign to drive certain dietary ingredients/supplements from the marketplace by simply declaring, without evidence or rule making, that certain dietary ingredients/supplements are not in fact dietary ingredients but rather unapproved food additives, deemed adulterated by statute. In the case of DMHA containing products, which pose no danger to consumers, the FDA has simply declared them, via a posting to its website, to be "adulterated" because DMHA is allegedly not a dietary ingredient marketed before October 15, 1994. *See* FDA Website Post, attached hereto as Exhibit 1. This has been accompanied by a campaign of intimidation against dietary supplement companies like Hi-Tech who include this ingredient in their products. For Hi-Tech and several of its competitors, this has taken the form of warning letters and pressure by the FDA to remove and destroy DMHA containing products. See, April 10, 2019 Warning Letter to Hi-Tech, attached hereto as Exhibit 2.

3. For Plaintiff Jared Wheat, the President and Chief Executive Officer of Hi-Tech, the stakes are even higher. Mr. Wheat is subject to an unrelated criminal prosecution for various fraud and other charges regarding dietary supplements set forth in a superseding indictment that was returned on September 28, 2017. See *United States v. Jared Wheat, et al.,* 1:17-cr-00229-AT-CMS, Northern District of Georgia, Doc. 7. Shortly after the superseding indictment was unsealed, Mr. Wheat posted an appearance bond. Among Mr. Wheat's bond conditions is the requirement that he not manufacture, distribute or sell "adulterated foods or misbranded drugs." *United States v. Jared Wheat, et al,* 1:17-cr-00229-AT-CMS, Northern District of Georgia, Doc. 22-1. Thus, Mr. Wheat faces the very real threat that the United States Attorney's Office for the Northern District of Georgia could move to revoke his bond based on nothing more than the FDA's assertion, without proof, that Hi-Tech's DMHA containing products are deemed adulterated by statute.

4. The FDA has declined to engage in the rule making process necessary to formally ban DMHA. Thus, there has been no public discussion or comment as to the scientific evidence regarding DMHA and its safety. DMHA, derived from walnuts, has existed in the food supply for many years and certainly before October 15, 1994. Hi-Tech has sold over a million bottles of dietary supplement products containing this ingredient for the past two years without any serious adverse event reports. Upon information and belief, Hi-Tech's competitors have sold millions of

bottles of DMHA containing products for the past five years without any serious adverse event reports. Plaintiffs respectfully request that the FDA's campaign of intimidation be enjoined and that, if the agency has scientific evidence which brings the safety of DMHA into question, that it disclose same and engage in the formal rule making process to ban the ingredient. Furthermore, Plaintiffs seek an express declaration that DMHA is a legitimate dietary ingredient, the presence of which in a dietary supplement product does **not** render that product an "adulterated food."

JURISDICTION AND VENUE

5. This case arises under the United States Constitution and the laws of the United States and presents a federal question within this Court's jurisdiction under Article III of the United States Constitution and 28 U.S.C. § 1331. The Court also has jurisdiction under the Administrative Procedures Act ("APA"), 5 U.S.C. § 702. The Court has authority to grant declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* Venue is proper in this district under 28 U.S.C. § 1391(e).

PARTIES

6. Plaintiff Hi-Tech is a Georgia corporation with its principal place of business in the State of Georgia. Hi-Tech is one of the largest manufacturers and distributors of dietary supplements in the United States. Hi-Tech sells its products to more than 100,000 retail locations including: GNC, CVS, Walgreen's, Wal-Mart,

K-Mart, Kroger and convenience stores nationwide. Hi-Tech also sells directly to consumers, healthcare practitioners, and food and dietary supplement companies. Hi-Tech also contract manufactures dietary supplement products for other companies and buys and sells raw ingredients for dietary supplement products as well. Several of Hi-Tech's products contain DMHA, including, for example, Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene.

7. Plaintiff Jared Wheat is the President and Chief Operating Officer of Hi-Tech.

8. Defendant Sharpless is the Acting Commissioner of the FDA. In his official capacity as the Commissioner, Defendant Sharpless is in whole or in part directly responsible for the decisions that are at issue in this lawsuit. Defendant Sharpless is sued in his official capacity only.

9. Defendant FDA is an agency within HHS and has direct responsibility for implementing the Dietary Supplement Health and Education Act (hereinafter "DSHEA"). Pub. L. No. 103-417, 108 Stat. 4325 (1994). FDA is responsible for enforcement of the various provisions of DSHEA in compliance with federal law.

10. Defendant Azar is the Secretary of HHS. In his official capacity as the Secretary of HHS, Defendant Azar is responsible for ensuring that agencies within the control of HHS, including the FDA, are in compliance with federal law and is in

whole or in part directly responsible for the decisions at issue in this lawsuit. Defendant Azar is sued in his official capacity only.

11. Defendant HHS is an agency of the United States Government. HHS is responsible for ensuring that agencies within the control of HHS, including the FDA, remain in compliance with federal law.

THE LEGAL FRAMEWORK FOR THE REGULATION OF DIETARY SUPPLEMENTS

12. Dietary supplements, including those manufactured, produced, marketed, distributed and sold by Plaintiff Hi-Tech, are regulated pursuant to DSHEA, which amended the Federal Food, Drug and Cosmetic Act ("FFDCA") in 1994.

13. Under DSHEA, a dietary supplement is deemed "adulterated" if it presents a "significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

14. Furthermore, under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs, unless the supplement's producer asserts disease claims that bring the supplement within the definition of a drug under the FFDCA. *See* 21 U.S.C. §§ 321(ff) (defining "dietary supplement"), (g)(1) (defining "drug").

See also 21 U.S.C. § 343(r)(6) (identifying claims which may be made by dietary supplement manufacturers and those claims which are prohibited).

15. Because dietary supplements are classified as foods, manufacturers and producers are **not** required to provide evidence of product safety or efficacy before marketing dietary supplement products. Dietary supplements are legally presumed to be safe. In any proceeding under DSHEA, the "United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f)(1). Defendants thus have the burden of proof in showing adulteration. Before commencing an action, the FDA must provide the responding party "appropriate notice and opportunity to present views" regarding the matter. 21 U.S.C. § 342(f)(2).

16. DSHEA covers "dietary ingredients." A dietary ingredient is defined as a "vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient [from the preceding categories]." 21 U.S.C. § 321(ff)(1). Dietary ingredients include both naturally occurring and synthetically produced versions of the same ingredient. The FDA has recognized the equivalence of natural vs. synthetically produced dietary ingredients in the context of several vitamins and other ingredients.

17. The above statutory framework applies generally to dietary ingredients marketed in the United States prior to October 15, 1994. Dietary ingredients introduced into the marketplace after that date, i.e. "new dietary ingredients" require notification to the FDA at least 75 days prior to the marketing of the ingredient with information regarding the ingredient's safety. 21 U.S.C. § 350b(a)(2).

18. The effect of the above requirements is that, typically, the FDA only regulates and/or prevents the sale of "adulterated" dietary supplements on a "product-by-product basis" rather than on a "class basis." To date, there has been only a single occasion in which the FDA has taken action against an entire class of dietary supplements through the above referenced procedures. *See Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk.* 69 Fed. Reg. 6788 (February 11, 2004), codified at 21 C.F.R. § 119.1. The FDA has **not** followed this procedure regarding dietary supplements that contain DMHA.

DMHA

19. As mentioned above, DMHA is a natural constituent of walnut trees (*Juglans regia).* Walnuts and the bark of the tree itself have been consumed by humans for many centuries. *Juglans regia* is found in many parts of Asia, Europe, Australia, New Zealand and the United States.

20. While there is a dearth of clinical studies of DMHA itself, there is a significant body of scientific evidence supporting the safety of DMHA for human consumption. For example, animal studies of DMHA showed it to have a very high LD50. "LD50" is the amount of a substance needed to cause the deaths of 50% of animals in a study group. In DMHA's case, a massive dose was required to achieve LD50 in a variety of animals. Similarly, animal studies show the effects of DMHA to be relatively benign. For example, in one animal study, DMHA's ability to increase blood pressure was only 1/500 to 1/1,000 that of epinephrine, a drug/hormone used to treat allergic reactions to food.

21. DMHA has an extensive history of use in dietary supplements. Plaintiffs have retained a leading dietary supplement scientist/regulatory expert to look at the issue of DMHA's classification as a dietary ingredient and its safety.

22. That expert concluded—after reviewing the relevant scientific literature on DMHA—that DMHA should be considered a dietary ingredient under DSHEA because it is found in multiple plants, each of which have a long history as part of the human diet.

23. In order to analyze the safety of DMHA, the expert reviewed, among other things, data from FDA's adverse event data base for 2014 to 2018 using the various synonyms for DMHA. No record of a single serious adverse event was found. A similar search of Canada's comparable data base also revealed no adverse

events for DMHA. Coupled with Hi-Tech's lack of any serious adverse event reports, this evidence supported the expert's conclusion that there is no reason to question the safety of DMHA.

24. Further support for the safety of DMHA can be found in the scientific research regarding another challenged dietary ingredient, DMAA, the status of which under DSHEA is currently pending before the Eleventh Circuit Court of Appeals. According to Plaintiffs' expert, while DMAA is not the chemical equivalent of DMHA, it does have a very similar structure and thus, the two ingredients could be expected to produce similar effects in humans. Multiple clinical studies of DMAA containing products found the ingredient to induce no harmful effects in humans. Most importantly, an extensive case control study of DMAA conducted by the Department of Defense found no link between DMAA consumption and adverse medical events.

THE FDA'S "CRACKDOWN" ON DIETARY SUPPLEMENTS

25. The FDA's action against DMHA is not the first time the agency has acted in an arbitrary and capricious manner, attempting to remove dietary ingredients/supplements from the marketplace without appropriate rule making or procedure. Regarding the similarly structured DMAA, in April 2012 the FDA effectively removed this dietary ingredient from the marketplace by sending out a series of warning letters to dietary supplement companies alleging, among other

things, that DMAA elevated blood pressure which could lead to heart attacks and that the ingredient was synthetically produced and therefore not a dietary ingredient. *See United States v. Undetermined quantities of all articles of finished and in-process foods, etc., et al.*, 1:13-cv-03675-WBH-JCF, Northern District of Georgia, Doc. 108-5. The agency brazenly admitted that it chose this truncated approach to the removal of DMAA, rather than formally banning the ingredient, because "The law requires FDA to follow certain lengthy steps before the agency can ban dietary supplements containing DMAA." See *United States v. Undetermined quantities of all articles of finished and in-process foods, etc., et al.*, 1:13-cv-03675-WBH-JCF, Northern District of Georgia, Doc. 108-6.

26. The FDA's warning letter campaign against DMAA was undertaken with the express purpose of circumventing the legal procedures outlined in DSHEA. The appropriateness of this approach is currently before the Eleventh Circuit.

27. Perhaps emboldened by its at least preliminary success regarding DMAA, the FDA has expanded its tactic of removing dietary ingredients/supplements of which it disapproves from the marketplace, regardless of the requirements of DSHEA. On April 16, 2019, under the guise of "modernizing the FDA's oversight of the dietary supplement industry" the agency announced the promulgation of a "Dietary Supplement Ingredient Advisory List" which lists ingredients that, according to the FDA, "do not appear to be lawful" and that dietary

supplement companies "**may wish** to avoid selling, making or distributing" products containing the ingredients. *See* FDA Statement and Advisory List attached hereto as Exhibit 3.

28. No public comment or input was solicited in creating the FDA's advisory list nor were any hearings held regarding the creation of same. The agency has not released any scientific or legal documentation supporting the inclusion of ingredients on this list other than prior warning letters. On information and belief, several of the ingredients on the FDA's Advisory List have been used by dietary supplement companies for decades, consumed by millions of consumers without serious adverse events, or other negative consequences.

29. At the same time of the announcement of its Advisory List, the FDA again trumpeted the warning letters issued regarding DMHA, alleging it was an unsafe food additive. *See* Exhibit 3. In essence, the FDA's expanded, aggressive approach to dietary supplement regulation has turned DSHEA on its head, attempting to shift to dietary supplement companies the burden of proving a dietary supplement ingredient is safe and lawful, rather than what is clearly called for by DSHEA, namely that dietary ingredients are foods which are presumed safe and that the FDA has the burden to demonstrate that they are unsafe and/or unlawful.

30. By issuing the warning letter regarding DMHA attached hereto as Exhibit 2, the FDA seeks to "expand the envelope" and further broaden its authority

over dietary supplements in direct contravention of DSHEA. It departs dramatically in form and substance from prior warning letters regarding dietary ingredients/supplements. Unlike many prior warning letters, the DMHA warning letter makes no specific claim that the ingredient is unsafe and describes no potential adverse consequences from consuming the ingredient. There is no allegation that DMHA is synthetically produced. There is no citation to any scientific study or literature. There is no allegation that Hi-Tech (or other companies) have made inappropriate or unsubstantiated claims regarding DMHA. In other words, the FDA has taken the unprecedented position that its assertion, without more, that an ingredient was not in the food supply before the effective date of DSHEA (October 15, 1994) is enough in and of itself to deem a product/ingredient unlawful and/or adulterated.

THE EFFECT OF THE FDA'S ACTION ON PLAINTIFFS

31. The warning letter sent to Plaintiffs demands that Wheat/Hi-Tech "immediately cease distribution" of any and all DMHA containing products. Moreover, as noted above, Mr. Wheat's release conditions in his unrelated criminal case forbid him from distributing "adulterated foods."

32. Based on the foregoing, there exists an actual controversy between the Plaintiffs Hi-Tech/Wheat and the Defendants regarding the FDA's circumvention of DSHEA and attempt to "ban" DMHA without an appropriate legal and scientific

review. Moreover, there is little doubt that the FDA will continue this inappropriate pattern of conduct against other companies that market or manufacture DMHA containing products. For Mr. Wheat personally there is the specter of incarceration absent a declaratory judgment.

33. Hi-Tech has an established and respected business reputation in the dietary supplement industry from the production, marketing, distribution and selling of dietary supplement products, including those with DMHA.

34. Hi-Tech stands to suffer immediate and irreparable harm to its business reputation should it be forced to cease the manufacturing, production, marketing, distribution and sales of dietary supplement products containing DMHA. Additionally, the existing inventory of Hi-Tech's DMHA containing products is worth millions and the products have a limited shelf life.

35. Hi-Tech also will suffer immediate and irreparable harm to its business reputation if it is forced to recall DMHA containing products which are lawfully in the marketplace.

36. Accordingly, Plaintiffs Hi-Tech and Jared Wheat seek declaratory and injunctive relief against the Defendants prohibiting them from circumventing DSHEA by using warning letters against DMHA containing products which have not been established to be either unsafe or "adulterated" or from seeking Mr. Wheat's incarceration for the sale/distribution of same.

CAUSES OF ACTION

A. Declaratory Relief Regarding the FDA's Action Against DMHA Containing Products.

37. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

38. As described herein, there exists an actual controversy of a justiciable nature between Plaintiffs and the Defendants. Pursuant to 28 U.S.C. §§ 2201-2202, Plaintiffs are entitled to a declaratory judgment declaring Plaintiffs' rights as follows:

a. Unless and until there has been a proper rule making procedure pursuant to DSHEA, Hi-Tech/Wheat may continue to market and manufacture DMHA containing products.

b. Unless and until there has been a proper rule making procedure pursuant to DSHEA, Defendants may not detain DMHA containing products marketed or manufactured by Hi-Tech.

c. Unless and until there has been a proper rule making procedure pursuant to DSHEA regarding the legality of DMHA, Defendants are estopped from claiming in any court that DMHA containing products are adulterated or misbranded.

WHEREFORE, the Plaintiffs demand judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMHA containing products unlawful and in violation of DSHEA and the APA;

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

c. Declaring the Defendants' actions against Plaintiffs as unlawful and in violation of DSHEA and the APA;

d. Granting Plaintiffs preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMHA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

B. Defendants Violated DSHEA and the APA by Attempting to Improperly Shadow-Ban DMHA without Engaging in the Proper Rule Making Process.

39. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

40. By proceeding against DMHA containing products via intimidating letters which lack supporting allegations and evidence, the Defendants have circumvented the statutory requirements of DSHEA. Moreover, they have improperly shifted the burden of proof as to the safety and lawfulness of DMHA containing products to the manufacturers and producers of dietary supplements containing DMHA.

41. Defendants have further indicated that Plaintiffs will be required to cease manufacturing, producing, marketing, distributing and selling DMHA

containing products. Defendants continue to disregard their statutory obligations under DSHEA by making these demands without formal rule making, the presentation of scientific evidence, or an opportunity for public review and comment. By such agency action, the Defendants are acting in a manner that is contrary to the established law, in violation of Section 706(2)(a) of the APA.

42. Furthermore, in taking the actions described above, the Defendants are acting in a manner in excess of the statutory authority and jurisdiction granted to the Defendants by Congress in violation of DSHEA and Section 706(2)(c) of the APA.

43. Finally, in taking the actions described above, the Defendants are acting in a manner inconsistent with DSHEA and thus, not in observance of the procedures required by law in violation of Section 706(2)(d) of the APA.

44. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

45. As a consequence of the above, the Defendants' actions are unlawful and must be set aside and prohibited under Sections 706(2)(a), (c) and (d) of the APA.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMHA containing products unlawful and in violation of DSHEA and the APA;

b. Forbidding the Defendnats from claiming in any court that DMHA containing products are adulterated or misbranded;

c. Declaring the Defendants' actions against Plaintiffs as unlawful and in violation of DSHEA and the APA;

d. Granting Plaintiffs preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMHA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

C. Under DSHEA, DMHA is Presumed to be a Safe Dietary Ingredient, and Defendants Violated DSHEA and the APA by Attempting to Shift the Burden on this Issue to Plaintiffs.

46. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

47. Under DSHEA, the Defendants have the burden to demonstrate that DMHA containing dietary supplements "present an unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

48. Defendants completely failed to meet this high burden in order to declare dietary supplements containing DMHA "adulterated" under DSHEA.

49. By proceeding against Hi-Tech and other manufacturers/marketers of DMHA containing products via warning letters without sufficient evidence, the Defendants distorted federal law and disregarded the Congressional mandate that placed the burden of proof upon the Defendants in connection with the prohibition of dietary supplements under DSHEA.

50. Specifically, the Defendants shifted the burden of proof to the manufacturers and producers of DMHA containing dietary supplements by implementing a "risk/benefit" analysis unauthorized by Congress. Under this impermissible analysis, a manufacturer or producer of dietary supplements containing DMHA must establish that the benefits of such products outweigh the risks associated with the use of such products.

51. Moreover, under this unauthorized concept of "risk/benefit," the Defendants simply have to show an extremely slight risk in order to justify the prohibition on the sale of dietary supplements containing DMHA.

52. In addition, the Defendants have further violated federal law by failing to reach a "dose-specific" determination of the presence of risk associated with the use of dietary supplements containing DMHA as required by DSHEA.

53. Under DSHEA, the Defendants have an affirmative duty to demonstrate a "significant or unreasonable" risk at a particular dose level in order to support a finding that a dietary supplement containing DMHA is adulterated.

54. In issuing warning letters against DMHA, the Defendants have ignored the express intent of Congress and simply relied upon an unfounded presumption that a safe level could not be determined. By failing to do so, the Defendants improperly placed the burden upon manufacturers and producers of dietary supplements containing DMHA to demonstrate that their respective products are safe at their recommended or suggested dosage levels. Such action by the Defendants is directly contrary to the statutory language placing the burden of proof on the government and to the intent of Congress in regulating dietary supplements as food.

55. The conduct of the Defendants in making their determinations in issuing warning letters, is in direct violation of DSHEA and the Defendants are acting in a manner that is contrary to the established law, in violation of Section 706(2)(a) of the APA.

56. In making the determinations described above, the Defendants are acting in a manner in excess of the statutory authority and jurisdiction granted to the Defendants by Congress in violation of DSHEA and Section 706(2)(c) of the APA.

57. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

58. Consequently, the Defendants' conduct in issuing warning letters regarding DMHA is unlawful and must be set aside under Section 706(2)(a)(c) of the APA.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMHA containing products unlawful and in violation of DSHEA and the APA;

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

c. Declaring the Defendants' actions against Plaintiffs as unlawful and in violation of DSHEA and the APA;

d. Granting Plaintiffs preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMHA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

D. Violation of Due Process Under the Fifth Amendment to the United States Constitution.

59. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

60. Defendants' actions as described herein constitute actions designed to deprive Plaintiffs of their due process rights under the Fifth Amendment to the Constitution of the United States.

61. Specifically, the Defendants' actions requiring Plaintiffs to cease manufacturing, producing, marketing, distributing and selling their DMHA containing dietary supplement products, deprive Plaintiffs of their due process rights in violation of the Fifth Amendment to the Constitution of the United States and in further violation of 5 U.S.C. § 706(2)(B).

62. Defendants' actions have injured and will continue to injure and will cause irreparable harm to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMHA containing products unlawful and in violation of DSHEA and the APA;

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

c. Declaring the Defendants' actions against Plaintiffs as unlawful and in violation of DSHEA and the APA;

d. Granting Plaintiffs preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMHA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

E. The Defendants' Actions Are Arbitrary and Capricious Under the APA.

63. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

64. The Defendants have failed to meet their burden of proof under DSHEA to demonstrate that Hi-Tech's DMHA containing products are not safe when used in accordance with the recommended dosage found on the products' labeling as required by DSHEA. 21 U.S.C. § 342(f)(1)(A).

65. Defendants have failed to meet their burden under DSHEA to prove that Hi-Tech's DMHA containing products "present an unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

66. The Defendants have attempted to avoid the high burden of proof placed upon them by resorting to a risk/benefit analysis not authorized by Congress under DSHEA whereby the Defendants simply have to show an extremely slight risk in order to justify the prohibition on the sale of dietary supplements containing DMHA.

67. By seeking to prevent Plaintiffs from marketing or selling dietary supplements containing DMHA without sufficient, credible evidence that demonstrates an "unreasonable risk" with the use of such dietary supplements at their recommended dosage level, the Defendants have acted arbitrarily and capriciously and have abused their discretion with respect to Plaintiffs.

68. Furthermore, by failing to follow the necessary procedural requirements as required by DSHEA, the Defendants have acted arbitrarily and capriciously and have abused their discretion with respect to Plaintiffs.

69. Consequently, the Defendants' enforcement actions against Plaintiffs including, but not limited to, the issuance of a warning letter, are unlawful and must be set aside under Section 706(2)(A) of the APA. Furthermore, by failing to meet their statutorily required burden of proof as established by DSHEA, the Defendants are prohibited from taking enforcement action(s) against Plaintiffs.

70. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMHA containing products unlawful and in violation of DSHEA and the APA;

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

c. Declaring the Defendants' actions against Plaintiffs as unlawful and in violation of DSHEA and the APA;

d. Granting Plaintiffs preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMHA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

Respectfully submitted,

/s/ Jack Wenik
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